

## Claims

1 1. A medical device for use within a body lumen of a patient, the device comprising:  
2 a first coil having a plurality of windings defining a first lumen and locatable on the  
3 proximal side of the external sphincter, the first coil having a distal end terminating on the  
4 proximal side of the external sphincter when the device is placed within the body of the patient;  
5 a second coil having a plurality of windings defining a second lumen and locatable on the  
6 distal side of the external sphincter, the second coil having a proximal end terminating on the  
7 distal side of the external sphincter when the device is placed within the body of the patient; and  
8 a connecting segment locatable in the external sphincter when the device is placed within  
9 the body of the patient, the connecting segment disposed between and coupling together the first  
10 and second coils.

1 2. The medical device of claim 1 further comprising a removal segment attached to a  
2 proximal end of the first coil.

1 3. The medical device of claim 2 wherein the removal segment is disposed within at least  
2 one of the first lumen and the second lumen.

1 4. The medical device of claim 3 wherein at least one of the first coil, the second coil, and  
2 the connecting segment further comprise an inner core and an outer coating covering at least a  
3 portion of the inner core.

1 5. The medical device of claim 4 wherein the inner core comprises a biocompatible  
2 material.

1 6. The medical device of claim 5 wherein the outer coating loses structural integrity during  
2 hydration.

1 7. The medical device of claim 6 wherein the outer coating is absorbed into the lumen of a  
2 patient at a predetermined degradation rate.

1 8. The medical device of claim 7 wherein the outer coating is selected from the group  
2 consisting of polyglycolic acid, polylactic acid, or a polymer.

1 9. The medical device of claim 4 wherein the outer coating is a polyimide.

1 10. The medical device of claim 8 wherein the outer coating further comprises a  
2 pharmaceutical.

1 11. The medical device of claim 4 wherein the windings of the first coil and the second coil  
2 are sized and configured to progressively uncoil from the proximal end of the first coil to a distal  
3 end of the second coil upon application of a continuous tensile force to the removal segment.

1 12. The medical device of claim 4 wherein the proximal end of the first coil comprises a  
2 frusto-conical shape.

1 13. The medical device of claim 4 wherein the windings of the first coil and the second coil  
2 are separated from each other by a distance in the range of from about 0.5 millimeters to about  
3 10 millimeters.

1 14. The medical device of claim 4 wherein a cross-sectional area of the outer coating is in the  
2 range of from about  $7.9 \times 10^{-3}$  millimeters<sup>2</sup> to about 7.1 millimeters<sup>2</sup>.

1 15. The medical device of claim 4 wherein the proximal end of the first coil and the distal  
2 end of the second coil include one or more hooks to permit connection to a delivery system.

1 16. A medical device for use within a body lumen of a patient, the device comprising:  
2 an inner core including a first coil defining a first lumen and having a proximal  
3 end and a distal end, a second coil defining a second lumen and having a proximal end  
4 and a distal end, and a connecting segment therebetween, the inner core comprising a  
5 plurality of spaced coil windings being sized and configured for placement and retention  
6 substantially within the urethra of a patient; and  
7 an outer coating layered upon at least a portion of the inner core for supporting  
8 the first lumen and the second lumen of the inner core when placed with the body lumen  
9 of the patient.

1 17. The medical device of claim 16 wherein the first coil, second coil and connecting  
2 segment are of unitary construction.

1 18. The medical device of claim 16 further comprising a removal segment attached to the  
2 proximal end of the first coil.

1 19. The medical device of claim 18 wherein the removal segment is disposed within at least  
2 one of the first lumen and the second lumen.

1 20. The medical device of claim 17 wherein the outer coating loses structural integrity during  
2 hydration.

1 21. The medical device of claim 16 wherein the inner core comprises a biocompatible  
2 material.

1 22. The medical device of claim 20 wherein the outer coating is absorbed into the lumen of a  
2 patient at a predetermined degradation rate.

1 23. The medical device of claim 22 wherein the outer coating is selected from the group  
2 consisting of polyglycolic acid, polylactic acid, or a polymer.

1 24. The medical device of claim 16 wherein the outer coating is a polyimide material.

1 25. The medical device of claim 16 wherein the outer coating further comprises a  
2 pharmaceutical.

1 26. The medical device of claim 16 wherein the windings are sized and configured to  
2 progressively uncoil from the proximal end of the first coil to the distal end of the second coil  
3 upon application of a continuous tensile force to the removal segment.

1 27. The medical device of claim 16 wherein the proximal end of the first coil further  
2 comprises a frusto-conical shape.

1 28. The medical device of claim 16 wherein windings of the first coil and the second coil are  
2 separated by a distance in the range of from about 0.5 millimeters to about 10 millimeters.

1 29. The medical device of claim 16 wherein a cross-sectional area of the outer coating is in  
2 the range of from about  $7.9 \times 10^{-3}$  millimeters<sup>2</sup> to about 7.1 millimeters<sup>2</sup>.

1 30. The medical device of claim 16 wherein the proximal end of the first coil and the distal  
2 end of the second coil includes one or more hooks to permit connection to a delivery system.

1 31. A method of maintaining the patency of a patient's urethra, the method comprising the  
2 steps of:

3 a. supporting the prostatic section of a the urethra with a first coil defining a first  
4 lumen and locatable on the proximal side of the external sphincter;

5 b. supporting the bulbar section of a the urethra with a second coil defining a second  
6 lumen and locatable on the distal side of the external sphincter; and

c. permitting substantially normal constriction of the external sphincter with a substantially uncoiled connecting segment disposed between and coupling the first coil and second coil.

32. The method of claim 31 further comprising the steps of:

a. providing a system comprising (1) a first element having an outer diameter smaller than the diameters of the first coil and the second coil and including a first end, a second end, and a connection member extending out from the first end and (2) a second element including a first end, a second end, and a connection member extending out from the first end, at least one of the first and second elements of the delivery system being rotatable;

b. placing the first element of the delivery system within the lumen of the first and second segments;

c. attaching the connection member of the first element to the proximal portion of the first segment;

d. attaching the connection member of the second element to the distal end of the second segment;

e. rotating at least one of the first and the second elements to further wind the one or more windings to reduce the width of the stent at least to an extent needed to pass the stent into the urethra of the patient; and

f. removing the delivery system completely from the lumens of the first and second segments and from the patient's urethra, thereby leaving the stent positioned within the patient's urinary system.

1 33. The method of claim 32 wherein the connection member of the first element comprises  
2 an arm extending radially outward from the first end and includes an opening sized to receive a  
3 hook extending from the proximal portion.

1 34. The method of claim 32 wherein the connection member of the second element  
2 comprises an arm extending radially outward from the first end and includes an opening sized to  
3 receive the hooks extending from the proximal portion of the first segment and the distal end of  
4 the second segment.